

# Health Plans and Drug Companies Dip Their Toes Into Value-Based Pricing

## The Pressure Is on P&T Committees to Monitor Utilization

Stephen Barlas

**T**he Harvard Pilgrim health plan opened a new front in the battle to contain drug prices in November when it announced a pioneering contract with Amgen. Amgen agreed to provide two “pay for performance” rebates if its evolocumab (Repatha), one of the two new proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors, failed to meet two separate thresholds.<sup>1</sup> PCSK9 inhibitors are a class of biotechnology medicines that have demonstrated a promising new approach for treating elevated low-density lipoprotein-cholesterol (LDL-C) in patients whose levels cannot be controlled by current therapies. The other PCSK9 inhibitor is alirocumab (Praluent, Sanofi-Aventis/Regeneron). Repatha costs \$14,100 and Praluent \$14,600, respectively, for a year’s supply.

To help control costs, Amgen agreed to provide Harvard Pilgrim with an enhanced discount if the reduction in LDL-C levels for the health plan’s members is less than that seen during clinical trials. The agreement also provides for additional discounts if utilization of the drug exceeds certain levels. The contract includes an “adherence” provision that conditions discounts on Harvard Pilgrim members taking the drug reliably. “With the cost of new specialty drugs skyrocketing, our arrangement with Amgen will help us contain premium costs for employers and members,” Harvard Pilgrim Chief Medical Officer Michael Sherman says.

Health insurers in the U.S. and abroad have signed previous agreements with pharmaceutical manufacturers described as either “value-based” or “performance-based” that include a sharing of risk. For example, Merck agreed to provide discounts to Cigna if A1C lab values for Cigna’s insured population improved taking the Merck diabetes drugs sitagliptin (Januvia) and sitagliptin/metformin (Janumet).<sup>2</sup> “We hope this agreement will become a model in the industry,” Eric Elliott, president of Cigna Pharmacy Management, said in 2009. However, the Harvard Pilgrim/Amgen agreement appears to be broader in a sense because it contains the potential “budget-based” discount. Januvia is not quite as expensive as Repatha and some new specialty drugs, such as Gilead Sciences’ hepatitis C medications sofosbuvir (Sovaldi) and sofosbuvir/ledipasvir (Harvoni). The website Good Rx lists the price for 30 Januvia 100-mg tablets at about \$340 a month at numerous retail locations, or about \$4,100 a year.

No one knows what level of discount Cigna has received from Merck for Januvia. Karen Eldred, a Cigna spokeswoman, says the company has not disclosed rebate information because “some contract details are proprietary.” Josh J.

Carlson, MPH, an Assistant Professor in the Pharmaceutical Outcomes Research and Policy Program at the University of Washington, participated in a webinar sponsored in November by the National Pharmaceutical Council (NPC), a research organization supported by large, research-intensive drug companies. The Cigna/Merck agreement on Januvia was discussed, but Carlson says neither has made data on the rebates available.

Nor will Harvard Pilgrim disclose the price per month or year it is paying Amgen for Repatha or the level of the two prospective discounts. Joan Fallon, a Harvard Pilgrim spokeswoman, says the terms of the contract are confidential. She explains that the health plan will make the determination as to whether either of the two discounts are triggered.

Whatever the final cost of Repatha to Harvard Pilgrim, it will obviously be the key to determining whether this is in fact a value-based contract. There is no guarantee that either of the two discount triggers will be reached, nor is it known how far below wholesale those discounts would drop Repatha’s price. “I’m guessing the discount was pretty modest off the top,” one industry expert speculates. “We’ll have to see what the performance part of the deal will actually yield beyond that.”

That final price will decide how affordable the drug is and whether consumers, health experts, and others deem it a good value. The Institute for Clinical and Economic Review (ICER), an independent, nonprofit research group, published a draft report this fall stating that based on its value-based methodology (explained below), Repatha and Praluent should cost \$2,177 a year.<sup>3</sup> In a detailed statement, Amgen argued that ICER’s assumptions and methodology have “significant errors and deficiencies.”<sup>4</sup>

The final price to Harvard Pilgrim aside, the contract does adopt a value *structure*, and by doing so it may become a model for other pharmaceutical companies. Robert Dubois, the NPC’s Chief Science Officer, says the Harvard Pilgrim/Amgen contract has many attractive aspects. “From a pharmaceutical company’s perspective, the agreement meets many of the characteristics of what a successful risk-sharing structure would look like,” Dubois notes. Moreover, in a marketing sense, Amgen has given Repatha a way to distinguish itself from Praluent.

These kinds of value-based deals will put new pressure on P&T committees. In the case of Repatha and Praluent, the issue of statin intolerance will come into play. Some people taking statins complain about lower-body aches and pains, which they attribute to the statin. That is often a misdiagnosis, but physicians may respond by switching the patient to another



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drug. A November 2015 Viewpoint article in the *Journal of the American Medical Association* stated:<sup>5</sup>

The hypothesis that statin-associated adverse effects are due to statins is often not conclusively tested, because many patients stop statins or switch to other lipid-lowering agents. The usual approach to treat statin-associated adverse effects is to switch patients to a different statin, particularly to a low-dose (or every-other-day or once-a-week) statin associated with a lower incidence of the adverse effect. However, that usual approach is predicted to change. Clinicians who are treating patients experiencing statin-associated symptoms will likely switch to a PCSK9 inhibitor without trying statin challenge–rechallenge, *de facto* failing to test the hypothesis of a causal role of statins for the patients' symptoms.

### A New Focus on Value-Based Contracts?

Although it will be some time until the final cost of Repatha to Harvard Pilgrim becomes known, it is not too early to wonder whether the agreement provides encouragement to other manufacturers, health plans, and policy-makers. Drug prices show no signs of moderating. In August, Aon PLC, a major consulting firm, released a survey of 60 leading health care vendors and their expected pharmacy increases in 2016 for plans being renewed in 2015.<sup>6</sup> Pharmacy costs, including specialty drugs, are expected to increase 10%, up from 6.3% in the prior year. Focusing on specialty pharmacy drugs, estimated costs jumped a whopping 22.7% in 2015, following an 18.2% increase in 2014. "There is a robust pipeline of specialty drugs, which is contributing to the dramatic spike we see in cost trend," said John Malley, leader of Aon Health's Innovation Pharmacy Team. While pharmacy rate increases continue to rise significantly, carriers are expecting moderate medical cost increases, according to Aon.

In a survey, the nonpartisan Kaiser Family Foundation found that 77% of Americans identified drug prices as their number-one health concern. Presidential candidates have added rhetoric around the issue to their stump speeches. As the political heat intensifies, the federal government has begun to stir. In letters on November 5, 2015, to Gilead Sciences, AbbVie, Johnson & Johnson, and Merck, Andy Slavitt, Acting Administrator of the Centers for Medicare and Medicaid Services (CMS), asked for information on value-based purchasing arrangements, if any, that are being offered to payers and state Medicaid agencies, and what the companies are doing to make their medications more affordable. Those letters referenced the companies' hepatitis C vaccines. Gilead's Harvoni and Sovaldi compete against AbbVie's ombitasvir/paritaprevir/ritonavir with dasabuvir (Viekira Pak) and ombitasvir/paritaprevir/ritonavir (Technivie). Johnson & Johnson sells simeprevir (Olysio). Merck's one-tablet grazoprevir/elbasvir has been awarded the Food and Drug Administration (FDA) breakthrough therapy designation but has not been approved yet. In a blog post on November 5, 2015, Slavitt said:

These medicines are changing the lives of many individuals, but they are also expensive, costing tens of thousands of dollars, sometimes even more than \$100,000 per patient. These costs have strained personal as well as public budgets, particularly state health care budgets. Our notice to state Medicaid directors reminds states of

their obligation to provide access to these promising therapies based on the medical evidence, and that they have tools available to manage their costs.

According to an analysis published by the *Annals of Internal Medicine*, 42 state Medicaid systems limit payment in some way for sofosbuvir. Two-thirds of states restrict who may prescribe it, and about three-quarters allow access only when liver damage has resulted in fibrosis or cirrhosis.<sup>7</sup>

### The Wheels Start to Turn

Slavitt's emerging exploration of value-based drug purchasing initiatives follows in the footsteps of other major moves in that direction. Express Scripts, the nation's largest pharmacy benefit manager (PBM), says it will offer an "indication-based formulary" in 2016, which it describes as paying for performance. Brian Henry, an Express Scripts spokesman, explains that an indication-based formulary "gives us the opportunity to be even more specific about determining the value of a drug based on the outcomes it delivers."

"Right now, we're paying top dollar for every indication, including indications where the outcomes for the patient are marginal," says Steve Miller, MD, Express Scripts' Senior Vice President and Chief Medical Officer. "Paying for performance of a therapy should align with the value that therapy delivers to each individual patient."

One of the experts Express Scripts is talking with is Steven Pearson, MD, Founder and President of ICER. But Henry declines to say whether Express Scripts will adopt the ICER methodology. "We do believe that there are a number of potential models that may leverage some sort of pay-for-performance idea," Henry states.

It is not just health plans and PBMs that are concerned about the escalating price of drugs in the outpatient setting. So, too, are hospitals, even though inpatient drug costs are bundled into the overall price the hospitals charge payers for an inpatient episode of care. Kasey Thompson, PharmD, Vice President of the Office of Policy, Planning, and Communications at the American Society of Health-System Pharmacists (ASHP), says, "Value-based purchasing in the context of 'in-patient drug purchasing' is an interesting concept, and something that I believe hospital P&T committees have been doing for decades as part of a sound formulary management process."

However, formulary management is just one aspect of a value-based drug purchasing approach. In the case of Repatha, for example, a key issue is who is prescribed the drug and whether other statins are tried when the first statin prescribed doesn't work, for whatever reason. That is a clinical issue, having more to do with the prescribing physician than the formulary. Moreover, P&T committees are not responsible for hammering out discounts for drugs. Dr. Thompson wonders whether hospitals have the same sway in that regard as large health plans and insurers, such as Harvard Pilgrim and Cigna. "There's probably a leverage question here. Do most hospitals/systems or even GPOs [group purchasing organizations] have the leverage to push the pharma companies to think about pricing in a more value-based way? I'm guessing a system like the VA [Veterans Administration] probably comes closest to having that kind of clout and/or negotiating power."

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Some of the larger multihospital systems might be as well," he explains.

### The ICER Price Calculation

Insurers who do have the muscle to negotiate risk-sharing agreements with drug companies will likely look to the ICER draft analysis of "reasonable" costs for Repatha and Praluent, which uses a calculation that resembles in some ways the one advanced last year by the American Society of Clinical Oncology (ASCO). It is based on a metric called quality-adjusted life years (QALYs). A QALY is a measure of disease burden, including both the quality and quantity of life lived. QALYs can provide an indication of the benefits obtained from medical procedures in terms of quality of life and survival. The QALY is often used in cost-effectiveness analyses to evaluate and compare the value of specific treatments for purposes of allocating resources across a health care system or systems. An intervention with a lower cost per QALY gained would be preferred over an intervention with a higher ratio.

One can view the use of costs in action in the ICER draft reports on Repatha and Praluent.<sup>3</sup> In their calculations, both ASCO, with its draft value framework, and the ICER look at the cost to buy the drug and the patient's out-of-pocket expense. "Those two factors are fine," explains Dan Ollendorf, ICER's Chief Review Officer, "but they are not the entire picture. Our analysis goes beyond the ASCO approach by taking a broader perspective not just looking at how much it costs to use the drug, but also additional costs from side effects as well as other savings, such as reductions in the number of heart attacks and strokes in the case of PCSK9 inhibitors."

ASCO's framework is in draft form, and the group won't use it to determine what it thinks might be a fair price, as ICER has. Mary Rappaport, an ASCO spokeswoman, says the value framework will ultimately form the basis of tools that doctors can use in the clinical setting with their patients to help make treatment decisions. The framework is being developed by an ASCO Value in Cancer Care Task Force chaired by Lowell Schnipper, MD, Chief of the Division of Hematology and Oncology at Beth Israel Deaconess Medical Center. The task force expects to come up with values for the clinical benefit, toxicity, and cost of a treatment, and then assign it a value "score."

The idea, apparently, is to use oncologists as the fulcrum in a transaction that sees them pressing P&T committees at the hospitals where they work to adjust formularies to accommodate these scores. ASCO cites as the genesis of its efforts a 2013 article in the *Journal of Clinical Oncology* (JCO) entitled "Cancer drugs in the United States: *Justum Pretium*—the just price."<sup>8</sup> Aristotle is credited with being the first to discuss the relationship between price and worth in his book *Justum Pretium*, the just price. Among other things, the article cites an October 2012 *New York Times* opinion piece that relates how a hospital formulary dropped ziv-aflibercept (Zaltrap, Sanofi-Aventis) from its formulary after a value analysis found it cost twice as much as bevacizumab (Avastin, Genentech) but with no difference in efficacy between the two. Within a week, Sanofi-Aventis dropped the price of ziv-aflibercept by 50%. "Thus, expert review of anticancer therapies for their cost-benefit ratios may influence institutional usage and drug

pricing while preserving a healthy profit margin for pharmaceutical companies," the JCO article stated.

While ASCO will not establish a "just" price for drugs, the ICER will. Its draft analysis determined that at their current prices of more than \$14,000 a year, the cost per QALY gained for both Repatha and Praluent was about \$300,000. "Our analyses suggested that, to meet commonly accepted thresholds of between \$50,000 and \$150,000 per QALY gained, the price would have to drop to between approximately \$3,000 to \$7,500 per year," Ollendorf states. The closer the annual cost of a drug comes to the \$50,000 figure, the tighter its cost-benefit ratio. The ICER said the price that best represents the overall benefits these drugs may bring to patients would be between \$3,615 and \$4,811, representing a 67% discount off the list price.

But ICER advocated a second level of additional discount. "Even if these drugs were used in just over 25% of eligible patients, then employers, insurers, and patients would need to spend on average more than \$20 billion a year for these drugs, a cost that would continue on into the future," says Dr. Pearson, ICER's founder. The report concludes that it would take a further reduction to an annual drug cost of \$2,177 for the total prices of these new drugs to reach a level at which doctors and insurers would not have to try to limit patient use in some way to keep overall health care cost growth within bounds. Dr. Pearson concludes, "Our draft report therefore suggests that \$2,177 is the price that should serve as an alarm bell—if the cost is more than \$2,177 a year, drug companies, doctors, insurers, and other parties may need to work together to determine ways to limit the use of these drugs, find savings in other parts of the health care system, or adopt other measures to help make these drugs more affordable."

Amgen takes issue with multiple aspects of the ICER analysis,<sup>4</sup> most importantly its failure to take into account the impact of P&T committee utilization policies. Amgen argues the report for PCSK9 inhibitors performs a cost-effectiveness evaluation that models extensive product uptake by a population at lower risk than the FDA label and real-world adoption would suggest. ICER uses a figure of 10 million people a year taking Repatha. That would equate, at \$14,600 a year, to a cost of \$146 billion, which comes out to more than a third of the entire U.S. expenditure on all medications. Amgen argues:

Such estimates garner headlines, but they do not encourage a balanced discussion about value or result in patient-centered decision-making. The ICER analysis assumes a worst-case scenario where there is no utilization management. Since such controls are common for biologics, this starting place is disconnected from the reality of the U.S. health care system.

### Does This Meet the Right Challenge?

Some people wonder whether frenzied efforts to lower specialty drug prices via value-based contracts are obfuscating a potentially more important challenge: reducing spending on clinical services that lack scientific evidence for improving individual or population health. Mark Fendrick, MD, Director of the Center for Value-Based Insurance Design (<http://vbidcenter.org>) and a Professor in the Departments of Internal Medicine and Health Management and Policy at the University of Michigan, explains that the federal government

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requires evidence from randomized controlled trials on safety and efficacy prior to approval only for the approximately 12% of U.S. health care costs accounted for by prescription drugs. “A similar evidentiary benchmark is not required for the entirety of the remaining 88% of spending, such as expenditures for clinician visits, laboratory tests, imaging, and surgical interventions,” he states. Dr. Fendrick says that reducing utilization of costly medical services of low value, such as antibiotic therapy for viral respiratory illness and magnetic resonance imaging for people suffering from musculoskeletal back pain, would free up significant dollars that could be spent on services for which solid evidence of health benefits exists, such as guideline-recommended drug treatments that are systematically underused in many chronic conditions, including heart disease, depression, diabetes, and human immunodeficiency virus.

Regardless of whether they are a small part of reducing high U.S. health care costs or a big part, value-based drug contracts will have to overcome some barriers before they are more widely used, not the least of them transparency. If no one knows how Cigna did in its agreement with Merck on Januvia, how can the utility of that contract be judged by third parties and altered, if necessary, to meet the needs of all the players in the game? Then there are the high administrative costs for such contracts that necessitate the development of reusable platforms, the difficulty of obtaining the necessary data (insurers generally have only claims data), and the need to involve physicians. These challenges are significant—but so is the opportunity.

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